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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
10/023,224	12/20/2001	Daniel M. Cimbora	2318-287-II	2665

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	5

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
10/023,224	CIMBORA ET AL.
Examiner	**Art Unit**
David J Steadman	1652

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-160* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-160 are pending in the application.

Election/Restrictions

[2] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 145-154, and 157-159, drawn to an isolated protein complex, a polypeptide, and a protein microarray, classified in class 530, subclass 350.

II. Claims 5, 6, 155 and 156, drawn to an antibody that is immunoreactive with a protein and a protein complex, classified in class 530, subclass 387.9.

III. Claims 27-37, drawn to a non-human animal model for a physiological disorder and a cell line obtained therefrom, classified in class 800, subclass 9.

IV. Claim 38, drawn to a cell line with a modified genome to produce at least one protein complex, classified in class 435, subclass 325.

V. Claim 39, drawn to a cell line with a modified genome to eliminate at least one protein of a protein complex, classified in class 435, subclass 325.

VI. Claims 40-45, 117-144, and 160, drawn to a composition and a host cell comprising a first expression vector and a second expression vector, an isolated nucleic acid, a nucleic acid vector, a host cell, a microarray, and a method for making a polypeptide, classified in class 435, subclass 69.1.

VII. Claims 51-52, 54-55, 57-58, 66-67, 69-70, 73-74, 76-77, 79-80, 82-83, and 87-88, drawn to a drug or modulator useful for treating a physiological disorder, classified in class 514, subclass 789.

VIII. Claims 7-16, drawn to a method for diagnosing a physiological disorder comprising assaying for the presence of a protein complex, classified in class 435, subclass 7.1.

IX. Claims 7-16, drawn to a method for diagnosing a physiological disorder comprising assaying for the ability of proteins to form a protein complex, classified in class 435, subclass 7.1.

X. Claims 7-26, drawn to a method for diagnosing a physiological disorder comprising assaying for a mutation in a gene encoding a protein of a protein complex, classified in class 435, subclass 6.

XI. Claims 46-50, 56, 59-65, 68, 71, 72, and 75, drawn to a method for screening for drug candidates or modulators capable of modulating a protein interaction or a method for identifying a compound that binds to a protein, classified in class 435, subclass 7.1.

XII. Claim 53, drawn to a method for screening for drug candidates useful in treating a physiological disorder, classified in class 435, subclass 7.1.

XIII. Claims 78 and 81, drawn to a method for screening for drug candidates or modulators capable of modulating a protein interaction or a method for identifying a compound that binds to a protein using atomic coordinates of a protein, classified in class 702, subclass 27.

XIV. Claims 84-86, drawn to a method for selecting modulators of a protein, classified in class 435, subclass 7.1.

XV. Claims 89-95 and 113-116, drawn to a method for modulating a protein complex, classified in class 530, subclass 350.

XVI. Claims 96-102, drawn to a method for modulating neuronal cell death in a patient, classified in class 530, subclass 350.

XVII. Claims 103-112, drawn to a method for treating a physiological disorder, classified in class 514, subclass 789.

[3] The inventions are distinct, each from the other because:

[4] The polynucleotide of Group VI, the polypeptide of Group I, the antibody of Group II, the non-human animal model of Group III, the cell line of Group IV, the cell line of Group V, and the drug of

Group VII each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide of Group VI has other utility besides encoding polypeptides such as a hybridization probe, the polypeptide of Group I can be made by another method such as purification from the natural source or chemical synthesis, and the antibody of Group II can be made by a protein other than the protein encoded by the polynucleotide of Group VI, such as a protein purified from the natural source or produced by chemical synthesis.

[5] The polypeptide of Group I and the methods of Groups VIII-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used as an antigen in the production of an antibody.

[6] The antibody of Group II is unrelated to the method(s) of Groups X-XIV as it is neither used nor made by the method(s) of Groups X-XIV.

[7] The antibody of Group II and the methods of Groups VIII, IX, and XV-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used as an affinity reagent in the purification of the polypeptide of Group I.

[8] The non-human animal model of Group III is unrelated to the method(s) of Group VIII-XVII as it is neither used nor made by the method(s) of Groups VIII-XVII.

[9] The cell line of Group IV is unrelated to the method(s) of Groups VIII-XVII as it is neither used nor made by the method(s) of Groups VIII-XVII.

[10] The cell line of Group V is unrelated to the method(s) of Groups VIII-XVII as it is neither used nor made by the method(s) of Groups VIII-XVII.

[11] The nucleic acid of Group VI is unrelated to the method(s) of Group VIII, IX, and XI-XIV as it is neither used nor made by the method(s) of Groups VIII, IX, and XI-XIV.

[12] The nucleic acid of Group VI and the methods of Groups X and XV-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group VI can be used for protein expression.

[13] The drug of Group VII is unrelated to the method(s) of Groups VIII-X as it is neither used nor made by the method(s) of Groups VIII-X.

[14] The drug of Group VII and the methods of Groups XI-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the drug of Group VII can be used as an affinity reagent in the purification of the polypeptide of Group I.

[15] The methods of Groups VIII-XVII are independent as they comprise different steps, utilize different products and yield different results.

[16] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XVII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and/or

sequence search for each Group and thus, co-examination of the inventions of Groups I-XVII would be a serious burden on the examiner.

[17] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[18] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

05/09/03